

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE  <b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )	1. CERTIFICATE NUMBER: 14-R-0035 CUSTOMER NUMBER: 130	FORM APPROVED OMB NO. 0579-0036 <div style="text-align: right;"><i>Kb</i></div>
University Of Massachusetts Medical School 55 Lake Avenue North Worcester, MA 01655  Telephone: (508) -856-3151		

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reaso such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs		0	29	0	29
5. Cats					
6. Guinea Pigs		464	720	703	1887
7. Hamsters		0	50	0	50
8. Rabbits		191	12		203
9. Non-human Primates	4	0	0	0	0
10. Sheep					
11. Pigs		11	42	0	53
12. Other Farm Animals					
13. Other Animals					

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
 ( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED  
11/9/07

(b)(6), (b)(7)c

*5/10/12*

## Column E Explanation

Registration Number 14-R-0035

Guinea Pigs

703 in Column E

All category E in vivo testing performed at the Massachusetts Biologic Laboratories (MBL), located at the University of Massachusetts Medical School - Jamaica Plain Campus, are death as an endpoint assays mandated by the Code of Federal Regulations. The assays are mandatory and required in order for MBL to maintain licensure to manufacture and distribute vaccine product.

### **Supporting documents for testing of Diphtheria/Tetanus vaccines;**

**NIH Minimum Requirements; Diphtheria Antitoxin, 2<sup>nd</sup> Revision, January 18, 1946**

**NIH Minimum Requirements; Diphtheria Toxoid, 4<sup>th</sup> Revision, March 1, 1947**

**NIH Minimum Requirements; Tetanus and Diphtheria Toxoids Combined Precipitated Adsorbed (For Adult Use), August 25, 1953**

**NIH Minimum Requirements; Tetanus and Diphtheria Toxoids Combined Precipitated Adsorbed (For Adult Use), Amendment No. 1, November 28, 1956**

**Guidelines for Interpretation of Potency Test Results for all Forms of Adsorbed Diphtheria and Tetanus Toxoids, FR Doc. 79-11451 Filled 4-12-1979**

**NIH Minimum Requirements; Tetanus Toxoid, 4<sup>th</sup> Revision, December 15, 1952**

**NIH Minimum Requirements; Tetanus Toxoid, 4<sup>th</sup> Revision, Amendment No. 1, April 8, 1954**